APPENDIX A

AMENDED OPINION

UNITED STATES DISTRICT COURT

DISTRICT OF MASSACHUSETTS

Criminal Action No. 59-257-S

June 8, 1962

UNITED STATES OF AMERICA,

v.

NATURE FOOD CENTRES, INC., a corporation, and HENRY K. ROSENBERGER, and ANDREW G. ROSENBERGER, individuals,

SWEENEY, CH. J. This criminal case was submitted to the Court on a stipulation of facts signed by all of the parties together with certain exhibits in the nature of the articles offered for sale and with lectures and class notes and other literature provided by the defendants. There are 13 counts in the information, and a finding of guilty is made as to each of the defendants in all of the counts.

I find from the stipulated facts that the articles shipped in interstate commerce were drugs within the meaning of the statute. I find that each was intended to be used for the treatment of one or more diseases. I find that each of the defendants violated 21 U. S. C. 352 in that the labeling (including the lectures, class notes and other

information disseminated at the lectures) did not bear adequate directions for the use of the drugs offered which were, therefore, within the meaning of the statute, misbranded. The legislation covering this offense must be given a liberal interpretation to effectuate its high purpose of protecting unwary consumers in vital matters of health. The very vague, general and sketchy references to the drugs in question in the lectures and in the class notes do not comply with this statute's direction for "adequate directions for use."

The defendants are ordered to appear before this Court for sentencing on Tuesday, June 19, 1962, at 11:30 A.M.

Appendix A

OPINION

UNITED STATES COURT OF APPEALS

FOR THE FIRST CIRCUIT

No. 6031.

NATURE FOOD CENTRES, INC., *et al.*,
Defendants-Appellants.

v.

UNITED STATES OF AMERICA,
Appellee.

APPEAL FROM THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MASSACHUSETTS

Before WOODBURY, Chief Judge, and HARTIGAN and ALDRICH, Circuit Judges.

Milton A. Bass, with whom Bass & Friend was on brief, for appellants.

William W. Goodrich, Assistant General Counsel, with whom W. Arthur Garrity, Jr., United States Attorney, Walter E. Byerley, Attorney, and Stanislaw R. J. Suchecki, Assistant U. S. Attorney, were on brief, for appellee.

OPINION OF THE COURT

November 13, 1962

ALDRICH, Circuit Judge. The defendants were charged in a 13-count information with introducing into interstate

commerce certain drugs misbranded within the meaning of 21 U.S.C. §352(f)(1), "in that [the] labeling failed to bear adequate directions for use in that the labeling of said drug failed to state the purposes, conditions, and diseases for which said drug was intended . . . ." The statutory language requires that the "labeling bears (1) adequate directions for use . . . .". In addition, the statute provides for the issuance of regulations. 21 U.S.C. §371 (a). The pertinent, applicable[1] regulation is as follows:

> "Statements of all conditions, purposes or uses for which such drug or device is intended, including conditions, purposes or uses for which it is prescribed, recommended, or suggested in its oral, written, printed, or graphic advertising . . . ." 21 C.F.R. §1.106(a)(1) (1955)

The case was tried to the court without jury on a stipulation of facts and exhibits. The court found the defendants guilty on all counts and they appeal.

The defendants complain at the outset of the court's findings of fact as being inconsistent with the government's charge, and allege that they require a dismissal. The findings may be not altogether clear, but the defendants' interpretation is unwarranted.[2] Furthermore,

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[1] Defendants, properly, do not question the validity of this regulation. *Colgrove* v. *United States*, 9 Cir., 1949, 176 F. 2d 614, *cert. den.* 338 U. S. 911; *cf. V. E. Irons, Inc.* v. *United States*, 1 Cir., 1957, 244 F. 2d 34, 44, *cert. den.* 354 U. S. 923.

[2] The court said, "The very vague, general and sketchy references to the drugs in question in the lectures and in the class notes do not comply . . . ." Possibly the court misspoke itself, because nothing could be less vague than the references in the lectures (as distinguished from the class notes) to the defendants' products. It is true that in many instances the benefits were vaguely expressed. However, in others they were not.

since all the facts were stipulated, we must regard the court's error, if any, on a subsidiary matter as not prejudicial. Defendants concede in their brief, although with perhaps some other matters in mind, "The stipulated facts are before this Court. Appellants agree with appellee that this Court of Appeals can examine and evaluate the evidence in precisely the same manner as the District Court did." We pass, therefore, to the merits.

Each count alleges, and the stipulation shows, that defendants shipped certain bottles containing tablets or capsules from Massachusetts to their place of business in Philadelphia, or Chicago, and that the labels on said bottles bore a name, such as Colex, C-Aminos, Hemo-Glo, B-Amino-Complex, GL-12, and the statement that it was a "dietary supplement" containing three to fourteen or more specified ingredients. The stipulation further shows that said products were offered for sale throughout the month of April 1958, at defendants' said places of business, and for three days near the end of the month at a lecture hall elsewhere in each city, where defendants gave a series of lectures. At each lecture there were available, at $1.50 each,[3] so-called "Class Notes on Health and Nutrition" relating to the lecture for the day. These notes were not available at defendants' said places of business. It is the government's position that the labels on the bottles failed to show the "purposes or uses" for which the drugs were "intended;" that the defendants did have various purposes, as disclosed by the lectures; and hence that the drugs were "misbranded."

[3] This statement as to availability and price is over-favorable to the defendants.

Appendix A

The defendants do not seriously contend that their products are not drugs within the act. See *United States v. Hohensee*, 3 Cir., 1957, 243 F.2d 367, *cert. den.*, 353 U.S. 976. Their position with respect to purchasers at their places of business who did not know of the lectures was that as to them they did not have the purposes the lectures disclosed, so that further "labeling" was not needed. "[T]here is not a scintilla of evidence that the product shipped to the stores was intended for any use other than that which appeared on its label—that is, as a dietary supplement." This contention is scarcely realistic. It can hardly be thought that in offering such esoteric products as Isoleucine, Methionine and Tryptophane, not to mention Lecithin and Glutamic Acid which, among others, were described on the bottle as "Need in human nutrition not established," defendants had no special purposes in mind. The regulations, *supra*, cover this matter precisely by permitting reference to "oral, written, printed, or graphic advertising." The government properly introduced the lectures, transcribed by a government agent who had paid the entrance fee, as evidence of defendants' intentions. *V. E. Irons, Inc.* v. *United States*, 1 Cir., 1957, 244 F.2d 34, 44, *cert. den.* 354 U.S. 923; *United States* v. *Hohensee*, *supra*. In them the defendants made fulsome claims as to the preventative and curative qualities of their various products.

Defendants say, alternatively, that the class notes repeated "coextensively" what was said in the lectures, and accordingly, by disclosing these same purposes, satisfied the statutory requirements of "labeling." This contention cannot be supported. In the first place, the contents of the notes fell far short of the lectures. In the lectures all of the products were mentioned by name.

Appendix A

In the notes reference was made only to various substances. Even if, which we may question, identification by ingredients was sufficient, the claims or purposes stated in the lectures and in the notes were substantially different. For example, in one of the lectures defendants represented that "[g]ray hair can be restored to its original color by . . . using Hemo-Glo." As allegedly "coextensive," defendants point to the following statements in the notes, "Vitamin . . . B-Complex, helps to prevent the graying of hair . . . . Para amino benzoic acid is also valuable for the prevention of gray hair . . . . Folic acid . . . also plays a part in retaining normal hair coloring . . . ." We suggest that "helping" prevent, and restoring, are manifestly different.

Again, in a lecture defendants represented that "C-Aminos tablets . . . would be ideal for anyone suffering from a lung condition." The only reference we discover in the notes to any lung curative feature of defendants' products is that pulmonary edema resulting from congestive heart failure may sometimes be "got rid of" by "diuretic drugs." Such a case is somewhat less broad than "anyone suffering from a lung condition."

As a further example, defendants, in a lecture, after referring to a case of a man who "[l]ost part of . . . smell after a very bad cold four years ago," said, "Lots of B-Complex factors and protein could probably be most helpful for this condition." The "coextensive" portion of the notes to which their brief refers us states that B Complex (a disclosed ingredient in one of their products) is helpful in the prevention of colds. Defendants add in their brief (without evidentiary support, or citation to the notes) that a bad cold may leave one with a partial

loss of smell. It is difficult for us to think how defendants can possibly believe this is equivalency.

Secondly, the notes would not satisfy the requirements of labeling even if they repeated the lectures verbatim. It is true that a "labeling," as distinguished from a "label," need not be physically attached to the container. It is enough if it accompanies it. 21 U.S.C. §321(m). *Kordel* v. *United States*, 1948, 335 U.S. 345; *V. E. Irons, Inc.* v. *United States*, *supra*; *Drown* v. *United States*, 9 Cir., 1952, 198 F.2d 999, *cert. den.* 344 U.S. 920. But although by "accompanying" documents a defendant may incur liability for false labeling even though they do not accompany all the products, this does not mean that independent documents can satisfy affirmative labeling obligations with respect to those products they do not accompany. *Alberty Food Products Co.* v. *United States*, 9 Cir., 1950, 185 F.2d 321. Some of defendants' products were destined for sale at the stores, where the notes were not available. Even the documents at the lecture halls were obtainable only upon the payment of an additional price. The obligation to brand products is not met by a course of conduct which will result in manifest lack of fulfillment.

Defendants make a number of other contentions which we refrain from commenting upon.

Judgment will be entered affirming the judgments of the District Court.

Appendix A

JUDGMENT

UNITED STATES COURT OF APPEALS

FOR THE FIRST CIRCUIT

No. 6031.

NATURE FOOD CENTRES, INC., *et al.*,
Defendants-Appellants,

v.

UNITED STATES OF AMERICA,
Appellee.

JUDGMENT

November 13, 1962

This cause came on to be heard on appeal from the United States District Court for the District of Massachusetts, and was argued by counsel.

Upon consideration whereof, It is now here ordered, adjudged and decreed as follows: The judgment of the District Court is affirmed.

By the Court:
s/ ROGER A. STINCHFIELD,
Clerk.

[cc. Messrs. Goodrich and Bass.]

Thereafter, on November 26, 1962, mandate was stayed until further order of the Court of Appeals for the First Circuit.

APPENDIX B

STATUTES

The Federal Food, Drug and Cosmetic Act of June 25, 1938, c. 675, 52 Stat. 1040 (21 U.S.C. 301, *et seq.*), provides in pertinent part:

SEC. 201(k)

The term "label" means a display of written, printed, or graphic matter upon the immediate container of any article; and a requirement made by or under authority of this Act that any word, statement, or other information appear on the label shall not be considered to be complied with unless such word, statement, or other information also appears on the outside container or wrapper, if any there be, of the retail package of such article, or is easily legible through the outside container or wrapper [21 U.S.C. 321 (k)].

SEC. 201(m)

The term "labeling" means all labels and other written, printed, or graphic matter (1) upon any article or any of its containers or wrappers, or (2) accompanying such article [21 U.S.C. 321(m)].

SEC. 502

A drug or device shall be deemed to be misbranded—

(a) If its labeling is false or misleading in any particular [21 U.S.C. 352(a)].

* * * * *

(d) If it is for use by man and contains any quantity of the narcotic or hypnotic substance alpha-eucaine, barbituric acid, beta-eucaine, bromal, cannabis, carbromal, chloral, coca, cocaine, codeine, heroin, marihuana, morphine, opium, paraldehyde, peyote, or sulfonmethane; or any chemical derivative of such substance, which derivative has been by the Secretary, after investigation, found to be, and by regulations designated as, habit forming; unless its label bears the name, and quantity or proportion of such substance or derivative and in juxtaposition therewith the statement "Warning—May be habit forming" [21 U.S.C. 352(d)].

(e) If it is a drug and is not designated solely by name recognized in an official compendium unless its label bears (1) the common or usual name of the drug, if such there be; and (2), in case it is fabricated from two or more ingredients, the common or usual name of each active ingredient, including the quantity, kind, and proportion of any alcohol, and also including whether active or not, the name and quantity or proportion of any bromides, ether, chloroform, acetanilid, acetophenetidin, amidopyrine, antipyrine, atropine, hyoscine, hyoscyamine, arsenic, digitalis glucosides, mercury, ouabain, strophanthin, strychnine, thyroid, or any derivative or preparation of any such substances contained therein: *Provided*, That to the extent that compliance with the requirements of clause (2) of this paragraph is impracticable, exemptions shall be established by regulations promulgated by the Secretary [21 U.S.C. 352(e)].

(f) Unless its labeling bears (1) adequate directions for use [21 U.S.C. 352(f)(1)].

Appendix B

REGULATION, SEC. 1.106(a)(1)

Drugs and devices; directions for use—(a) *Adequate directions for use.* "Adequate directions for use" means directions under which the layman can use a drug or device safely and for the purposes for which it is intended. Directions for use may be inadequate because (among other reasons) of omission, in whole or in part, or incorrect specification of:

(1) Statements of all conditions, purposes, or uses for which such drug or device is intended, including conditions, purposes, or uses for which it is prescribed, recommended, or suggested in its oral, written, printed, or graphic advertising, and conditions, purposes, or uses for which the drug or device is commonly used; except that such statements shall not refer to conditions, uses, or purposes for which the drug or device can be safely used only under the supervision of a practitioner licensed by law and for which it is advertised solely to such practitioner [21 CFR 1.106(a)(1)].